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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/797,481	03/10/2004	John G. Stark	3223.01US02	3292
24113	7590	08/11/2005	EXAMINER	
PATTERSON, THUENTE, SKAAR & CHRISTENSEN, P.A. 4800 IDS CENTER 80 SOUTH 8TH STREET MINNEAPOLIS, MN 55402-2100			REIMERS, ANNETTE R	
			ART UNIT	PAPER NUMBER
			3732	

DATE MAILED: 08/11/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/797,481

Applicant(s)

STARK, JOHN G.

Examiner

Annette R. Reimers

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-24 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-24 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 10 March 2004 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 06/13/05.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: ____.

DETAILED ACTION

Drawings

The drawings are objected to under 37 CFR 1.84(h)(5) because Figures 9 and 14 show modified forms of construction in the same view. In other words, Figures 9 and 14 appear to contain a separate figures and each figure should be labeled separately.

The drawings are further objected to as failing to comply with 37 CFR 1.84(p)(5) because they do not include the following reference sign(s) mentioned in the description: Reference numbers 260 and 316 are not included in the drawings.

The drawings are further objected to because the drawings appear to be informal and are difficult to understand. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended."

If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency.

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Additional replacement sheets may be necessary to show the renumbering of the remaining figures. The replacement sheet(s) should be labeled "Replacement Sheet" in the page header (as per 37 CFR 1.84(c)) so as not to obstruct any portion of the drawing figures. If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

The specification is objected to because reference number 130, line 28 of page 7 and lines 3 and 4 of page 11, has inconsistent terminology, i.e. warnings and instructions. Please clarify whether reference number 130 refers to warnings or instructions or both. In addition, reference numbers 262, lines 1 and 4 of page 12, respectively, has inconsistent terminology, i.e. head and screw. Please clarify whether reference number 262 refers to head or screw. In addition, the word "cannula", line 11 of page 8 is misspelled.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-11 and 12-20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter, which the applicant regards as the invention.

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In claim 1, line 3, "the sacroiliac joint " lacks proper antecedent basis.

In claim 12, line 1, "the immobilization" lacks proper antecedent basis.

In claim 18, line 1, "the tip" lacks proper antecedent basis.

In claim 19, line 1, "the threads" lack proper antecedent basis.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-5 and 8-11 are rejected under 35 U.S.C. 102(b) as being anticipated by the Kambin (U.S. Patent Number 6,175,758).

Kambin discloses a kit comprising an unthreaded pin, 56, a threaded, cannulated, self-tapping screw, 58, a cutting guide, 126, a drill bit, 38 and a cannula 124 (see Figures 2, 4-6, 14 and 17). The screw has a central canal for immobilization of a sacroiliac joint with a taper of at least about 1 degree and a dimension suitable for insertion into the sacroiliac joint of a human patient (see Figures 6 and 8).

Claims 12-24 are rejected under 35 U.S.C. 102(b) as being anticipated by the Bowman et al. (U.S. Patent Number 4,950,270).

Bowman et al disclose a biocompatible, fluted screw, 10, with a central canal for immobilization of a sacroiliac joint with a taper of at least about 1 degree and a dimension suitable for insertion into the sacroiliac joint of a human patient (see Figures

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1 and 2). Regarding method claims 21-23, the method for immobilizing a patient's sacroiliac joint is inherently performed using the device of Bowman et al. (see Figure 1).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 15-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bowman et al. (U.S. Patent Number 4,950,270).

Bowman et al. disclose the claimed invention except the taper of the screw being from about 2 degrees to about 30 degrees, the length of the screw being from about 4 inches to about 10 inches and the widest thickness of the screw being from about 1.4mm to about 16mm. It would have been an obvious matter of design choice to one skilled in the art at the time the invention was made to construct the device of Bowman et al. having the taper of the screw being from about 2 degrees to about 30 degrees, the length of the screw being from about 4 inches to about 10 inches and the widest thickness of the screw being from about 1.4mm to about 16mm since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

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Claims 6 and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kambin (U.S. Patent Number 6,175,758) in view of Bowman et al. (U.S. Patent Number 4,950,270).

Kambin discloses the claimed invention except for the screw being associated with or coated with a biologically active agent. Bowman discloses a screw and teaches that the screw is constructed and/or coated with a biocompatible material and teaches the use of biocompatible material to allow for permanent or long term emplacement in association with cancellous bone and soft tissues and to promote osteointegration (see Column 3, lines 13-17). It would have been obvious to one skilled in the art at the time the invention was made to construct the device of Kambin with the screw being associated with or coated with a biologically active agent in view of Bowman, in order to allow for permanent or long term emplacement in association with cancellous bone and soft tissues and to promote osteointegration.

Claim 24 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bowman et al. (U.S. Patent Number 4,950,270) in view of Kambin (U.S. Patent Number 6,175,758)

Bowman discloses the claimed method except for the use of imaging. Kambin discloses the use of CT and conventional radiographic visualization and teaches the use of CT and conventional radiographic visualization in order to determine insertion points and angles for a guide pin (see Column 2, lines 54-57). It would have been obvious to one skilled in the art at the time the invention was made to incorporate in the

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method of Bowman the use of imaging in view of Kambin, in order to determine insertion points and angles for a guide pin.

Conclusion


The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. See PTO 892 for art cited of interest.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Annette R. Reimers whose telephone number is (571) 272-7135. The examiner can normally be reached on Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on (571) 272-4719. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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EDUARDO C. ROBERT
PRIMARY EXAMINER